

WHAT ARE THE FACTORS THAT AFFECT FILTERING FACEPIECE RESPIRATOR COMFORT & TOLERABILITY AND HOW DO WE MEASURE THEM?

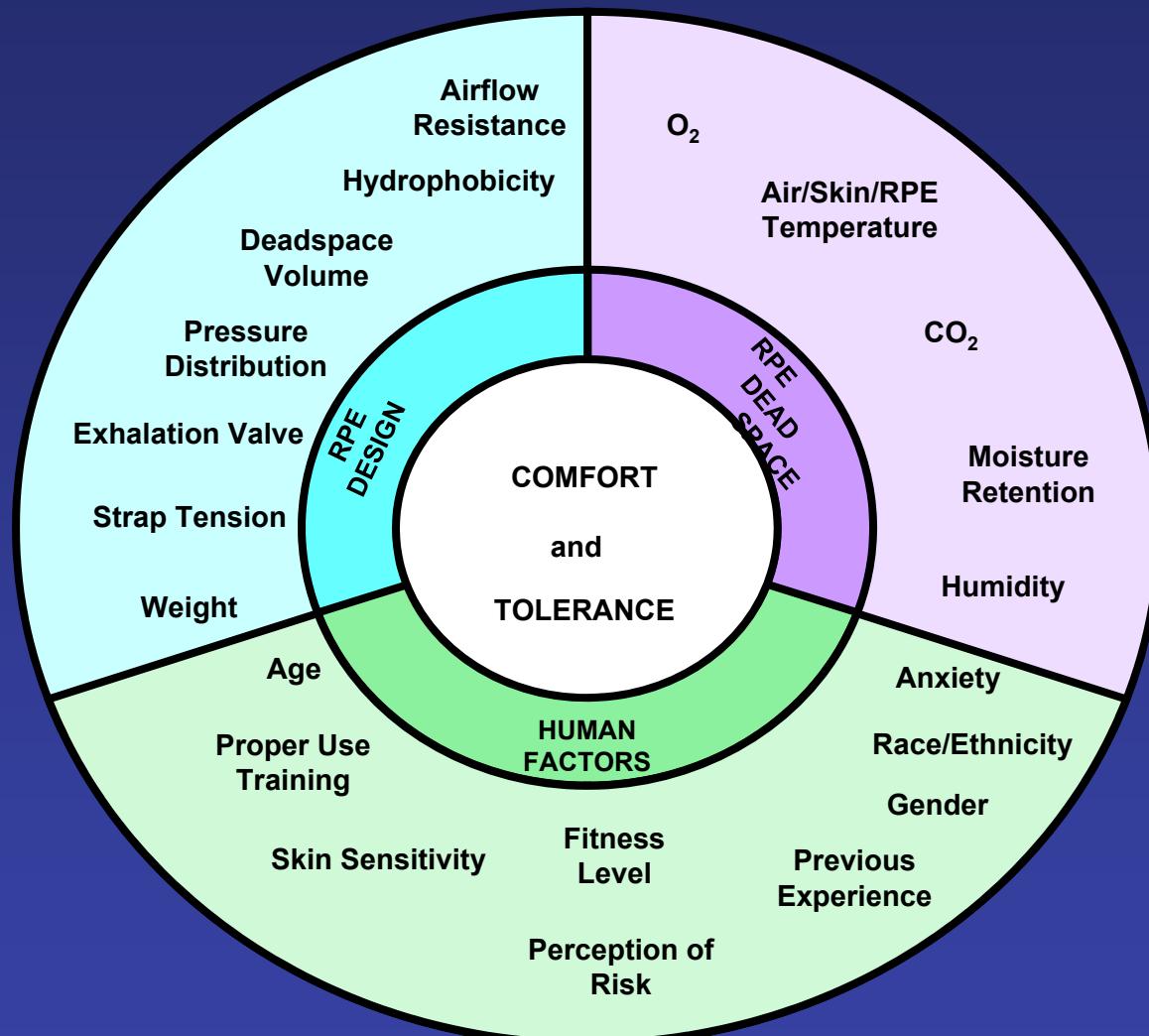
NIOSH Personal Protective Technology Program Healthcare Stakeholder Meeting

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PROTECTIVE FACEMASK COMFORT AND TOLERANCE: RESEARCH DIRECTIONS





PROTECTIVE FACEMASK DEADSPACE PARAMETERS

DEADSPACE TEMPERATURE AND HUMIDITY

- **Methodology:** measured every 20 seconds (user defined response time) over one hour at a low-moderate work rate using the i-Button, a semiconductor temperature and RH sensor (i-Button, Dallas) that incorporates a real-time clock, memory, and 3V lithium battery encased in a small (16 × 6 mm) stainless steel can (temperature range -40°C to 85°C).
- **Results:**

PPE	Deadspace Temp °C (°F)	Deadspace Humidity %	Respirator Heat Index °C (°F)
Surgical Mask	32.7 (90.86)	91.4	53 (127)
N95 FFR (Model A)	33.4 (92.12)	88.9	55 (131)
N95 FFR (Model B)	33.8 (92.84)	91.9	59 (138)
N95 FFR/EV (Model A)	32.9 (91.22)	89.2	53 (127)
N95 FFR/EV (Model B)	33.8 (92.84)	86.9	56 (132)



- **Relevance:** N95 FFR with an exhalation valve resulted in significantly lower deadspace temperature but had no significant impact on deadspace humidity. Is discomfort related to facial heat, inhaled air temp, brain warming?

Roberge RJ, Kim J-H, Benson S. (2012) N95 filtering facepiece respirator deadspace temperature and humidity. *J Occup Environ Hyg* 9:166-171.



Roberge RJ, Kim J-H, Benson SM. (2012) Absence of consequential changes in physiological, thermal and subjective responses from wearing a surgical mask. *Resp Physiol & Neurobiol* 181: 29-35.

PROTECTIVE FACEMASK EFFECT ON COVERED (DEADSPACE) SKIN TEMPERATURE

- **Methodology:** deadspace skin temperatures were measured using Vital Sense® (Philips Respironics, Bend, OR) hypoallergenic, 57.2 mm diameter x 5.3 mm thickness water resistant, disposable wireless sensors.
- **Results:**



PPE	Temperature °C (°F) @ 3.5 mph x 1 h	
	Control	Trial
Surgical Mask	32.44 (90.39)	33.17 (91.70)
N95 Filtering Facepiece Respirator (Model A)	32.65 (90.77)	33.68 (92.62)
N95 Filtering Facepiece Respirator (Model B)	32.65 (90.77)	34.68 (94.42)
N95 Filtering Facepiece Respirator with Exhalation Valve (Model A)	32.65 (90.77)	33.34 (90.01)
N95 Filtering Facepiece Respirator with Exhalation Valve (Model B)	32.65 (90.77)	33.73 (92.71)



- **Relevance:** the facial skin covered by an N95 FFR increases in temperature because of the increased heat and humidity of the respirator dead space that is due to accumulation of exhaled warm, humidified air from the respiratory tract and barrier interference with sweat evaporation and heat convection.

1. Roberge RJ, Kim J-H, Benson SM. *Absence of consequential changes in physiological, thermal and subjective responses from wearing a surgical mask.* Resp Physiol Neurobiol 2012;181:29-35
2. Roberge RJ, Benson S, Kim J-H. *Thermal burden of N95 filtering facepiece respirators.* Ann Occup Hyg 2012 56: 808-814.

RESPIRATOR DEADSPACE CO₂ & O₂ LEVELS

- **Methodology:** continuous measurement of mixed inhalation/exhalation deadspace air utilizing AEI Technologies P-61B CO₂ sensor and N-22M O₂ sensor attached to a sampling port in the N95 FFRs during low-moderate work for one hour.
- **Results:**

PPE	O ₂ level	CO ₂ level
N95 FFR	16.6%±0.6	2.8±0.4
N95 FFR/EV	17.2±1.1	3.0±0.5
N95 FFR/SM	16.4%±0.7	3.0±0.4
N95 FFR/SM/EV	16.2%±0.6	2.9±0.3
EAPR	17.8±0.6	2.4±0.3



- **Relevance:** mixed inhalation/exhalation deadspace CO₂ and O₂ levels are above and below, respectively, OSHA workplace standards. SpO₂ is well maintained and tcPCO₂ levels rarely increase >2-3 mm Hg in healthy individuals over one hour of use.

1) Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. (2010) Physiological impact of the N95 filtering facepiece respirator on healthcare workers. *Resp Care* 55: 569-577.

2) Roberge RJ, Coca A, Williams WJ, Palmiero AJ, Powell JB. (2010) Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers. *Respirology* 15: 516-521.

3) Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. (2010) Reusable elastomeric air-purifying: Physiologic impact on health care workers. *Am J Infect Control* 38:381-386.



N95 FFR DESIGN AND STRUCTURAL FEATURES

N95 FFR MOISTURE RETENTION

- **Methodology:** N95 FFRs were weighed on a calibrated, Fisher Scientific accu 6201 scale before and after human and non-human (Automated Breathing and Metabolic Simulator) studies of 1 - 4 hrs duration at low and moderate work rates.
- **Results:** multiple studies show that moisture retention averages 0.1 – 0.2 gm H₂O over 1 – 4 hours.
- **Relevance:** modern N95 FFRs do not retain significant moisture due to their thinness, porosity, and the hydrophobicity of polypropylene, the major filter component.



1) Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. (2010) *Physiological impact of the N95 filtering facepiece respirator on healthcare workers*. *Respir Care* 55: 569-577.

2) Roberge RJ, Coca A, Williams WJ, Palmiero AJ, Powell JB. (2010) *Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers*. *Respirology* 15: 516-521.

3) Roberge RJ, Bayer E, Powell JB, Coca A, Roberge MR, Benson SM. (2010) *Effect of exhaled moisture on breathing resistance of N95 filtering facepiece respirators*. *Ann Occup Hyg* 54: 671-677.

4) Roberge R, Benson S, Kim J-H. (2012) *Thermal burden of N95 filtering facepiece respirators*. *Ann Occup Hyg* 56:808-814.

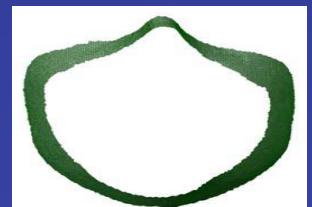
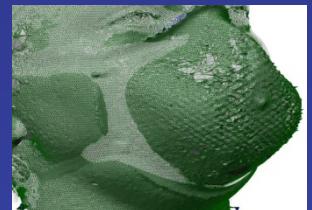
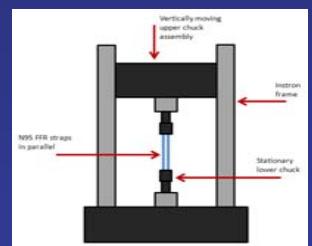
N95 FFR STRAP TENSION

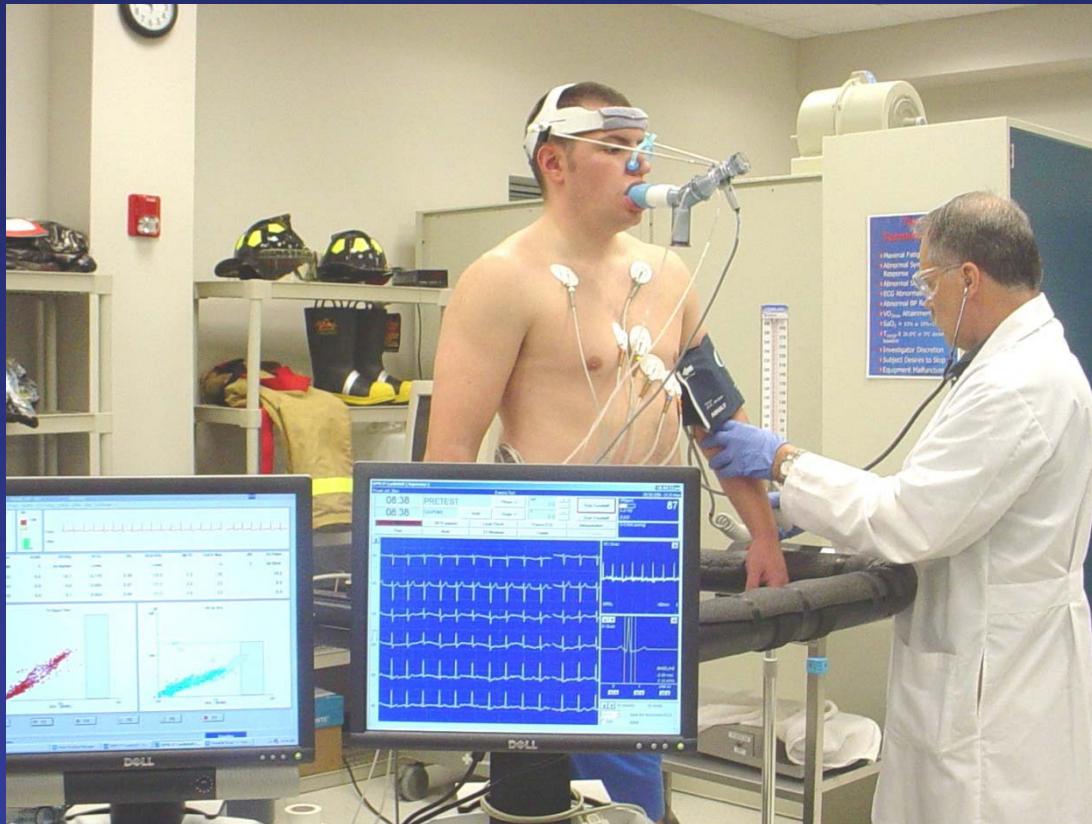
- **Methodology:** the length of N95 FFR straps (marked at 1 cm increments) was measured with stereophotogrammetry pre- and-post donning to determine strain. This strain data was then programmed into software connected to an Instron tensometer that was used to test N95 FFR straps that were strained for 15 minutes followed by 15 minutes of no strain. Five replicates of each strap were measured.
- **Results:** Upper straps of a trifold model of N95 FFR displayed the lowest tension (~4.2 Newtons/M² [0.43 mm H₂O pressure]).
- **Relevance:** The restorative forces developed in relation to N95 FFR strap tension are important for development of an adequate face seal. N95 FFRs with lower tension were still able to pass fit testing. Lower tension = more comfort.

1) Roberge R, Niezgoda G, Benson S. (2012) Analysis of forces generated by N95 filtering facepiece respirator tethering devices: a pilot study. *J Occup Environ Hyg* 9: 517-523.

2) Niezgoda G, Kim J-H, Roberge RJ, Benson SM. (2013) Flat fold and cup-shaped N95 filtering facepiece respirator face seal area and pressure determinations: a stereophotogrammetry study. *J Occup Environ Hyg* (in press, August 2013 release)

3) Niezgoda G, Benson SM, Eimer BC, Robrge RJ. (2013) Forces generated by N95 filtering facepiece respirator straps. *J Intern Soc Resp Protect* (in press, June/July, 2013 release)



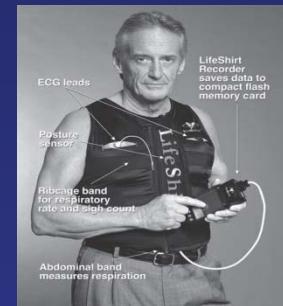


PROTECTIVE FACE MASK IMPACT ON HUMAN PHYSIOLOGY

CARDIOPULMONARY VARIABLES

- **Methodology:** respiratory rate and tidal volume were measured with the LifeShirt® plethysmographic vest (no longer in production) at one hour (low work rate). O₂ saturation, transcutaneous CO₂ and heart rate were measured with the Tosca heated, ear-mounted sensor.
- **Results**

PARAMETER	CONTROL	N95 FFR	N95 FFR/EV	Elastomeric
Respiratory rate	27.7	26.6	25.5	22.7
Tidal volume	864	945	932	941
Heart rate	101	106	106	101
O ₂ saturation	98.5	98.4	98.2	98.3
Transcutaneous CO ₂	40.8	42.0	42.6	43.8



- **Relevance:** at low and low-moderate work rates, use of a respirator results in a decrease in RR compensated for by a slight increase in the tidal volume. Heart rates are related more to the work rate than the respirator. O₂ saturation is not impacted and there is mild CO₂ retention.

1) Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. (2010) Physiological impact of the N95 filtering facepiece respirator on healthcare workers. *Resp Care* 55: 569-577.

2) Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. (2010) Reusable elastomeric air-purifying: Physiologic impact on health care workers. *Am J Infect Control* 38:381-386.

N95 FFR AND SURGICAL MASK IMPACT ON CORE TEMPERATURE

- **Methodology:** measured over one hour at a low-moderate work rate with the ingestible Jonah® core temperature pill (Philips Respironics, Bend, OR).
- **Results**

PPE	Control	Core temp @ 1h
N95 FFR (A)	37.77	37.70
N95 FFR/EV (A)	37.77	37.75
N95 FFR (B)	37.77	37.81
N95 FFR/EV (B)	37.77	37.78
Surgical mask	37.77	37.90



- **Relevance:** respiration accounts for ~10% of total body heat loss so that at low-moderate work rates there is little impact on core temperature. At these work rates, exhalation valves offer no improvement in core temperature effects.

1) Roberge RJ, Benson S, Kim J-H. Thermal burden of N95 filtering facepiece respirators. Ann Occup Hyg 2012 56: 808-814

FFR BREATHING RESISTANCE

- **Methodology:** breathing resistance measured with a Validyne (Northridge, CA) Model DP45 low pressure inline transducer over 30 second periods of nasal and oral breathing wearing prototype FFRs with resistances of 3mm, 6mm and 9mm at sedentary (standing) and low-moderate (bicycle ergometer) work rates.
- **Results (unpublished)**

Parameter	Sedentary (standing) mm H ₂ O pressure		Low-Moderate Work Rate mm H ₂ O pressure	
Resistance	Nasal Inhalation	Nasal exhalation	Nasal inhalation	Nasal Exhalation
3mm	-1.19 ±0.57	0.50 ±0.66	-2.31 ±0.83	1.51 ±2.02
6mm	-3.41 ±1.14	2.03 ±0.77	-5.01 ±1.37	3.37 ±1.46
9mm	-3.25 ±1.21	1.73 ±0.76	-5.04 ±1.50	3.38 ±1.50
Parameter	Sedentary (standing)		Low-Moderate Work Rate	
Resistance	Oral inhalation	Oral exhalation	Oral inhalation	Oral exhalation
3mm	-1.72 ±0.67	0.94 ±0.65	-2.94 ±0.99	2.00 ±1.05
6mm	-3.68 ±1.19	2.48 ±0.95	-6.04 ±0.91	4.44 ±1.17
9mm	-3.88 ±1.61	2.71 ±1.16	-6.34 ±1.68	4.99 ±1.81

- **Relevance:** no significant difference in 6 mm and 9mm prototype respirators, but 3mm is significantly different than both, but no physiological or subjective differences between the three. Decreasing resistance <9mm may not be beneficial because the threshold level for inspiratory resistance is 6.0 – 7.6 mm H₂O/L·sec⁻¹.

1) Kim J-H, Roberge RJ, Powell JB, Shaffer RE, Ylitalo CM, Sebastian JN. (2013) Breathing resistance of filtering facepiece respirators: how low should we go? Manuscript pending submission to journal.

2) Roberge RJ, Kim J-H, Powell JB, Shaffer RE, Ylitalo CM, Sebastian JN. (2013) Impact of different breathing resistances on subjective and physiological responses to filtering facepiece respirators. Manuscript pending submission to journal.

SUBJECTIVE MEASURE OF PPE COMFORT OVER 1H AT LOW-MODERATE WORK RATES

CONDITION	Comfort Score	Exertion Score
Controls	5.7*	9.6**
Surg Mask	5.8*	10.2**
Controls	1.1§	1.0¶
N95 FFR	1.6§	1.1¶
N95 FFR/EV	1.4§	0.9¶
N95 FFR/SM	1.5§	1.6¶
N95 FFR/EV/SM	1.7§	0.9¶
EAPR	1.4§	1.0¶



*Frank Scale (0-4 “coldest ever” to “slightly cold”; 5 “neither hot nor cold”; 6-10 “slightly hot” to “the hottest you have ever been”)

**Borg Scale (6-12 “no exertion” to “fairly light exertion; 13-16 “somewhat hard” to “hard”; 17-20 “very hard” to very, very hard”)

§Modified Frank Comfort Scale (1 = “very slight” or “not at all uncomfortable”; 2 = “a little uncomfortable”; 3 = “moderately uncomfortable”; 4 = “quite a bit uncomfortable”; 5 = “extremely uncomfortable”)

¶Modified Borg Perceived Exertion Scale (0 = “extremely easy”; 1 = “easy”; 2 = “somewhat easy”; 3 = “somewhat hard”; 4 = “hard”; 5 = “extremely hard”)

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